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## PATENT COOPERATION TREATY

PCT/US2004/042660

From the INTERNATIONAL BUREAU

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## PCT

NOTIFICATION CONCERNING  
TRANSMITTAL OF COPY OF INTERNATIONAL  
PRELIMINARY REPORT ON PATENTABILITY  
(CHAPTER I OF THE PATENT COOPERATION  
TREATY)

(PCT Rule 44bis.1(c))

To:

BAKER, C. Hunter  
Patent Group  
Choate, Hall & Stewart LLP  
Two International Place  
Boston, MA 02110  
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)

29 June 2006 (29.06.2006)

Applicant's or agent's file reference

2005735-0002 ✓

## IMPORTANT NOTICE

International application No.

PCT/US2004/042660

International filing date (day/month/year)

17 December 2004 (17.12.2004)

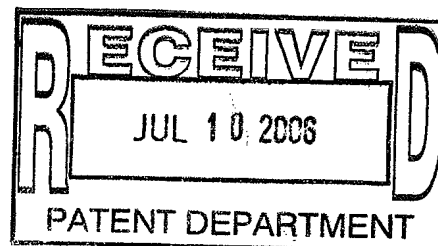
Priority date (day/month/year)

19 December 2003 (19.12.2003)

Applicant

OSIO CORP. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Dorothee Mülhausen

Facsimile No.+41 22 740 14 35

Facsimile No.+41 22 338 87 40

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

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|--|--|--|
| Applicant's or agent's file reference<br>2005735-0002  | <b>FOR FURTHER ACTION</b>  | See item 4 below   |
| International application No.<br>PCT/US2004/042660   | International filing date ( <i>day/month/year</i> )<br>17 December 2004 (17.12.2004) | Priority date ( <i>day/month/year</i> )<br>19 December 2003 (19.12.2003) |
| International Patent Classification (8th edition unless older edition indicated)<br>See relevant information in Form PCT/ISA/237 |  |  |
| Applicant<br>OSIO CORP.  |  |  |

|                                     |  |   |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
|-------------------------------------|--|---|-----------|---------------------|--------------------------|------------|----------|--------------------------|-------------|--|--------------------------|------------|----------------------------|-------------------------------------|-----------|---|--------------------------|------------|-------------------------|--------------------------|-------------|--|--------------------------|--------------|---|
| 1.                                  | This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).  |   |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| 2.                                  | This REPORT consists of a total of 4 sheets, including this cover sheet.   |   |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
|                                     | In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.  |   |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| 3.                                  | <p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> | <input checked="" type="checkbox"/>   | Box No. I | Basis of the report | <input type="checkbox"/> | Box No. II | Priority | <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | <input type="checkbox"/> | Box No. IV | Lack of unity of invention | <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | <input type="checkbox"/> | Box No. VI | Certain documents cited | <input type="checkbox"/> | Box No. VII | Certain defects in the international application | <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |
| <input checked="" type="checkbox"/> | Box No. I  | Basis of the report   |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. II   | Priority  |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input checked="" type="checkbox"/> | Box No. V  | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. VIII   | Certain observations on the international application   |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| 4.                                  | The International Bureau will communicate this report to designated Offices in accordance with Rules 44 <i>bis</i> .3(c) and 93 <i>bis</i> .1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44 <i>bis</i> .2).   |   |           |                     |                          |            |          |                          |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |

|  |   |
|--|---|
| <p style="text-align: center;">The International Bureau of WIPO<br/>34, chemin des Colombettes<br/>1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 740 14 35</p> | <p>Date of issuance of this report<br/>20 June 2006 (20.06.2006)</p> <p>Authorized officer<br/><br/><b>Dorothee Mülhausen</b></p> <p>Telephone No. +41 22 338 87 40</p> |
|--|---|

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
C. HUNTER BAKER  
CHOATE, HALL & STEWART  
EXCHANGE PLACE  
53 STATE STREET  
BOSTON, MA 02109

**PCT**

REC'D 08 AUG 2005

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) 04 AUG 2005

Applicant's or agent's file reference

2005735-0002

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US04/42660

International filing date (day/month/year)

17 December 2004 (17.12.2004)

Priority date (day/month/year)

19 December 2003 (19.12.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 9/00; A61F 2/00 and US Cl.: 424/400, 427

Applicant

OSIO CORP.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-8300

Authorized officer

Humera N. Sheikh

Telephone No. (571) 272-1600

Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/42660

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing.  
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format  
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US04/42660

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)

Claims 1-49 YES  
Claims NONE NO

Inventive step (IS)

Claims 1-49 YES  
Claims NONE NO

Industrial applicability (IA)

Claims 1-49 YES  
Claims NONE NO

2. Citations and explanations:

Claims 1-49 meet the criteria of PCT Article 33(2)-33(3) since the prior art does not disclose nor fairly suggest a method for treating an ophthalmic condition comprising the instantly claimed process steps.

Claims 1-49 meet the criteria of PCT Article 33(4) since the claimed system has industrial applicability in drug delivery applications.